Best Available Cop

13 CLAIMS

- 1. Meldonium salts of the general formula: X⁻(CH₃)₃N⁺NHCH₂CH₂COOH wherein X is an anion selected from the group consisting of hydrogen phosphate, hydrogen fumarate, hydrogen oxalate, hydrogen maleate, hydrogen pamoate, orotate, galactarate, sulfate, dichloroacetate, hydrogen galactarate, fumarate, taurate, maleate, hydrogen aspartate, creatinate, hydrogen sulfate, magnesium succinate, hydrogen citrate, citrate, succinate, hydrogen succinate, adipinate, hydrogen tartrate and lactate anions
- 2. A salt of claim 1 is meldonium hydrogen phosphate
- 3. A salt of claim 1 is meldonium fumarate
- 4. A salt of claim 1 is meldonium hydrogen fumarate
- 5. A salt of claim 1 is meldonium hydrogen oxalate
- 6. A salt of claim 1 is meldonium maleate
- 7. A salt of claim 1 is meldonium hydrogen maleate
- 8. A salt of claim 1 is meldonium hydrogen pamoate
- 9. A salt of claim 1 is meldonium orotate
- 10. A salt of claim 1 is meldonium dichloroacetate
- 11. A salt of claim 1 is meldonium galactarate
- 12. A salt of claim 1 is meldonium hydrogen galactarate
- 13. A salt of claim 1 is meldonium hydrogen aspartate
- 14. A salt of claim 1 is meldonium creatinate
- 15. A salt of claim 1 is meldonium sulphate
- 16. A salt of claim 1 is meldonium hydrogen sulphate
- 17. A salt of claim 1 is meldonium citrate
- 18. A salt of claim 1 is meldonium hydrogen citrate
- 19. A salt of claim 1 is meldonium succinate
- 20. A salt of claim 1 is meldonium hydrogen succinate
- 21. A salt of claim 1 is meldonium magnesium succinate

Best Available Cop

- 22. A salt of claim 1 is meldonium adipinate
- 23. A salt of claim 1 is meldonium taurate
- 24. A salt of claim 1 is meldonium hydrogen tartrate
- 25. A salt of claim 1 is meldonium lactate
- 26. The pharmaceutical composition comprising one of salts from claim 1, which is intended for oral or sublingual administration and is in the form of tablets, with or without coating, capsules, caplets, dragees, granules, powder or solution, which contain 0.01-0.5 g of the active system in every tablet, capsule, dragee, granule or powder dose, or also as a 0.5-40% solution or syrup for oral administration.
- 27. The pharmaceutical composition according to claim 26, wherein the pharmaceutically acceptable carrier is selected from the group consisting of one or more of the following: stearic acid and its salts, lactose, glucose, saccharose, starch, talc, vegetable oils, polyethylene glycols, microcrystalline cellulose, aerosil, aromatizers, flavoring agents, colorants, ethyl alcohol and water.
- 28. The pharmaceutical composition according to claim 1, which is intended for parenteral administration and is in a solution for injection, which contains 0.5-40% by weight of the active system and a pharmaceutically acceptable solvent.
- 29. The pharmaceutical composition according to claim 28, wherein the pharmaceutically acceptable solvent is selected from the group consisting of one or more of the following: distilled water, isotonic solution, buffer solution and glucose solution.
- 30. The pharmaceutical composition according to claim 1, which is intended for transcutaneous administration of the active system in the form of an ointment, cream, gel, solution or plaster, which contains 0.5-40% by weight of the active system, and a pharmaceutically acceptable carrier.
- 31. The pharmaceutical composition according to claim 30, wherein the pharmaceutically acceptable carrier is selected from the group consisting of one or more of the following: water, polyethylene glycols 400, 1500 and 4000, vegetable oils, fats, glycerine, preservants, emulgators, stabilizers, porous polymer material, dimethylsulphoxide, alcohol and water.
- 32. The pharmaceutical composition according to claim 1, which is intended for rectal administration of the active system in the form of suppositories or microenema, which contains 0.5-40% by weight of the active system and a pharmaceutically acceptable carrier.

- 33. The pharmaceutical composition according to claim 32, wherein the pharmaceutically acceptable carrier is selected from the group consisting of one or more of the following: water, polyethylene glycols 400, 1500 and 4000, vegetable oils, fats, glycerine, preservants, emulgators and stabilizers.
- 34. Use of Meldonium salt of the general formula: X (CH₃)₃N NHCH₂CH₂COOH wherein X is an anion selected from the group consisting of mono-substituted fumaric acid, mono-substituted phosphoric acid, mono-substituted oxalic acid, mono-substituted maleic acid un mono- and/or di-substituted galactaric, pamoic acids and orotic acid, for the manufacture a pharmaceutical composition for the 1 per day administration.
- 35. A process for producing of any of Meldonium salts of claim 1 of general formula:

X (CH₃)₃N NHCH₂CH₂COOH

wherein X is an anion selected from the group consisting of hydrogen phosphate, hydrogen fumarate, hydrogen oxalate, hydrogen maleate, hydrogen pamoate, orotate, galactarate, sulfate, dichloroacetate, hydrogen galactarate, fumarate, taurate, maleate, hydrogen aspartate, creatinate, hydrogen sulfate, magnesium succinate, hydrogen citrate, citrate, succinate, hydrogen succinate, adipinate, hydrogen tartrate and lactate anions; and

- (a) dissolving in per se known manner Meldonium in water or other appropriate solvent, an equimolar quantity of a polybasic acid selected from the group of fumaric acid, phosphoric acid, aspartic acid, citric acid, lactic acid, maleic acid, oxalic acid, or orotic acid (the latter is taken in semi-molar quantity) is adding; and
- (b) the mixture is stirring at temperature from 20 to 50°C till the corresponding salt is formed; and
- (c) Meldonium salt is evaporating to dryness if necessary; and
- (d) in case of need the obtained salt recrystallising from a suitable solvent.